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REC'D 10 DEC 2004

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RFW/B45320	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP 03/10349	International filing date (day/month/year) 15.09.2003	Priority date (day/month/year) 17.09.2002
International Patent Classification (IPC) or both national classification and IPC B65G17/32		
Applicant GLAXOSMITHKLINE BIOLOGICALS S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
 - This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 6 sheets.
3. This report contains indications relating to the following items:
 - I Basis of the opinion
 - II Priority
 - III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV Lack of unity of invention
 - V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI Certain documents cited
 - VII Certain defects in the international application
 - VIII Certain observations on the international application

Date of submission of the demand 22.03.2004	Date of completion of this report 09.12.2004
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I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-33 as originally filed

Claims, Numbers

1-33 filed with telefax on 25.11.2004

Drawings, Sheets

1-16 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

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5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

the entire international application,

claims Nos. 24

because:

the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for the said claims Nos. 24

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

the written form has not been furnished or does not comply with the Standard.

the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

restricted the claims.

paid additional fees.

paid additional fees under protest.

neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

complied with.

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not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

all parts.

the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Yes: Claims	1-23,25-33
	No: Claims	
Inventive step (IS)	Yes: Claims	1-23,25-33
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-23,25-33
	No: Claims	

2. Citations and explanations**see separate sheet**

Item IV:

1. The application lacks unity within the meaning of Rule 13 PCT for the following reasons:
 - a) The subject-matter of claims 1-21 and 25 (invention 1) concerns a holding means for an article and conveyor system, the holding means comprising a base part and a grip part;
 - b) the subject-matter of claims 22 and 23 (invention 2) concerns a conveyor system and process for filling a vial through a hollow needle; and
 - c) the subject-matter of claims 26-33 (invention 3) concerns a processing station for performing an operation on an article in a laminar flow of purified air, an aerodynamic shroud being placed around the processing apparatus.

There are no common inventive features linking the independent claims of the three inventions, such that the examining division considers that the separate inventions are not so linked as to form a single general inventive concept (Rule 13.1 PCT).

Item V:

2. The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: US-A-3 881 763
D2: WO 02 064439 A
D3: US-A-2 503 147
D4: US-A-6 098 676
D5: EP-A-0 096 336.

3. Invention 1 (claims 1-21, 25)

- 3.1 Document D1 discloses a holding means (chuck) suitable for lifting articles 124 having upward and downward facing surfaces onto a conveyor 116 for transporting the articles thereon, comprising:

a base (receiver 72 and resilient disc 80) suitable for the upward facing surface to sit upon;

a grip part 88 positioned relatively downwardly of the base and suitable to bear on the downward facing surface;

the base and grip part being moveable so that the article may be positioned between the base and the grip part, and the base and grip part may then be brought closer together to grip the article between the base and the grip part, and subsequently moved further apart to release the article (see figs 9 & 10 A, B, C, D, E).

However, the conveyor 116,118 of D1 is described as an overhead conveyor and operates by lifting the articles off a lower conveyor 122, whereas the subject-matter solves the problem of holding articles onto a conveyor.

None of the available prior art show or suggest the combination of features of claim 1 for holding articles onto a conveyor.

The subject-matter of claim 1 is therefore new and inventive within the meaning of Article 33(2) and (3) PCT.

- 3.2 Claims 2-21 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.
- 3.3 The process of claim 25 (dependent on the conveying system of claim 14 which is dependent on the holding means according to claim 1) uses the holding means of claim 1 and is therefore also novel and inventive.

4. Invention 2 (claims 22 and 23)

- 4.1 Document D3 discloses a conveyor system (racks 24 and endless chains 32) provided with a processing station (filling machine) to perform a process in which a vial 12 with its closure 14 made of a self sealing material such as rubber is punctured by passing a hollow filling needle 114 through the closure, a material introduced into the vial via the needle and the needle withdrawn, provided with means 64 to resist the upward force of withdrawing the filling needle (col. 6, lines 51-53, "first the injecting means is raised, and then the positioning frame 64").

The subject-matter of claim 22 differs from D3 in that the vial closure is made of a heat-fusible puncturable material and that the means to resist the upward force of withdrawing the filling needle hold the vial adjacent to the base of the vial.

This feature, which avoids the positioning of any holding means near to the vial mouth, is not known nor suggested by the available prior art.

The subject-matter of claim 22 is therefore new and inventive within the meaning of Article 33(2) and (3) PCT.

4.2 Claim 23 is dependent on claim 22 and as such also meets the requirements of the PCT with respect to novelty and inventive step.

5. Invention 3 (claims 26-33)

5.1 Document D4 discloses a processing station (fill-seal machine) for performing an operation on an article in a flow of purified air, which comprises:
- a processing apparatus for performing the operation upon the article, having an aerodynamic shroud (duct 32) around at least part of the apparatus.

The subject-matter of independent claim 26 differs from the known processing station of D4 in that the operation is carried out in a laminar upstream to downstream direction flow of purified air, and that the aerodynamic shroud around at least part of the apparatus is positioned such that a leading surface of the shroud is upstream of the apparatus.

The object of the aerodynamic shroud being to improve the laminar flow of purified air through the system.

Even though D5 discloses a perpendicular (left to right) laminar flow around containers to be filled, there is no suggestion from the available prior art to position an aerodynamic shroud such that a leading surface of the shroud is upstream of the apparatus.

Claim 26 is therefore new and inventive within the meaning of Article 33(2) and (3) PCT.

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5.2 Claims 27-33 are dependent on claim 26 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

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Claims.

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1. A holding means for holding articles having upward and downward facing surfaces onto a conveyor for transporting the articles thereon comprises;
 - 5 a base suitable for the downward facing surface to sit upon;
 - a grip part positioned relatively upwardly of the base and suitable to bear on the upward facing surface;
 - the base and/or grip part being moveable so that the article may be positioned between the base and the grip part, and the base and grip part may then
 - 10 be brought closer together to grip the article between the base and the grip part, and subsequently moved further apart to release the article.
2. A holding means according to claim 1 which comprises;
 - 15 a base having an upper part able to mate against a downward facing surface of an article,
 - and a grip part having a grip means able to mate against an upward facing surface of the article, the grip part being moveable relative to the base between upper and lower positions of the grip part, such that when the grip part is in its upper position there is a gap between the grip means and the upper part of the base
 - 20 into which gap at least part of the article may be placed, and when the grip part is in the lower position the grip means bears on the article and the downward facing surface of the article mates with the upper part of the base so that the article is held between the grip means and the base.
- 25 3. A holding means according to claim 1 or 2 adapted and suitable for gripping a pharmaceutical vial.
4. A holding means according to claim 3 adapted and suitable for gripping a vial carried in a carrier, the holding means being arranged to grip the vial carrier.

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5. A holding means according to claim 2, 3 or 4 wherein the grip part comprises an up-down extending shaft having a grip means adjacent the upper end of the shaft.
- 5 6. A holding means according to claim 5 wherein the grip means comprises a grip arm connected with the shaft and extending in a direction transverse to the shaft up-down direction, the grip arm being able to bear upon the article.
- 10 7. A holding means according to claim 6 wherein the grip means comprises two grip arms, between which the article may fit, with both arms extending in the transverse direction.
- 15 8. A holding means according to claim 6 or 7 wherein the grip part also comprises a support for the article which can fit underneath the article and support it whilst the grip part is in its upper position.
9. A holding means according to claim 8 wherein the support comprises one or more support arm that extends transverse to the up-down direction of the shaft to a remote end of the support arm.
- 20 10. A holding means according to any one of claims 2 to 9 wherein the base includes a guide to support and guide the grip part in its upward and downward movement between upper and lower positions.
- 25 11. A holding means according to any one of the preceding claims wherein the grip part is biased toward its lower position.
12. A holding means according to any one of claims 8 to 11 wherein the base has a receiving cavity for the support, and into which the support may be received when 30 the grip part is in its lower position.

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13. A holding means according to claim 12 wherein the up-down depth dimension of the receiving cavity is greater than the up-down thickness dimension of the support so that when the support is received in the receiving cavity with the grip part in its lower position the upper surface of the support is below the upper surface of the upper part of the base.

14. A conveyor system for the transport of articles in a conveying direction, provided with one or more holding means as claimed in any one of claims 1 - 13.

10 15. A conveyor system according to claim 14 incorporating a loader means adjacent to the conveyor and arranged to carry an article into a position relative to the holding means when the grip means is in its upper position, such that the downward facing surface of the article is above the upper part of the base and the upward facing surface of the article is below the grip means.

15 16. A conveyor system according to claim 14 or 15 incorporating an unloader means adjacent to the conveyor and arranged to unload articles from the holding means, being configured to receive an article gripped by the holding means, prior to movement of the grip part into its upward position to release the article from the holding means.

20 17. A conveyor system according to claim 14, 15 or 16 provided with one or more processing station arranged adjacent to the conveyor to perform one or more operation on articles carried by the conveyor.

25 18. A conveyor system according to claim 17 wherein a processing station is configured to perform a vial-filling process in which a vial with a closure made of a heat-fusible puncturable material is conveyed by the conveyor to a position adjacent the processing station, and the processing station punctures the vial closure by passing a hollow filling needle through the closure, introduces a material into the vial via the needle, and withdraws the needle.

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19. A conveyor system according to claim 17 or 18 wherein a processing station is configured to perform a process in which a puncture hole in a vial closure made of a heat- fusible puncturable material is sealed using a source of heat.

5 20. A conveyor system for the transport of vials with their closure made of a heat- fusible puncturable material in a conveying direction, provided with one or more holding means as claimed in claim 1 further provided with one or more processing station at which is situated a means for passing a hollow filling needle through the closure, introducing a material into the vial via the needle, and 10 withdrawing the needle.

21. A conveyor system according to claim 20 additionally comprising a processing station at which is situated a means for sealing the residual puncture left by the needle using a source of heat.

15 22. A conveyor system provided with a processing station to perform a process in which a vial with its closure made of a heat- fusible puncturable material is punctured by passing a hollow filling needle through the closure, a material introduced into the vial via the needle and the needle then withdrawn, provided with 20 means to resist the upward force of withdrawing the filling needle, said means comprising a means which holds the vial adjacent to the base of the vial.

23. A conveyor system according to claim 22 wherein said which holds the vial adjacent to the base of the vial comprises a carrier in which the lower part of the 25 vial body sits and having an upward facing surface, and a holding means which bears upon the upward facing surface of the carrier.

24. A conveyor system provided with a processing station to perform a process in which a vial with its closure made of a heat- fusible puncturable material is punctured by passing a hollow filling needle through the closure, a material introduced into the vial via the needle and the needle then withdrawn, provided with 30 means to resist the upward force of withdrawing the filling needle, said means

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comprising a means which holds the vial at a position which is downstream relative to the closure in a downwardly moving flow of purified air.

25. A process in which a vial with a closure made of a heat-fusible puncturable material is conveyed to a position adjacent a processing station which punctures the vial closure by passing a hollow filling needle through the closure, introduces a material into the vial via the needle, and withdraws the needle, or adjacent a processing station which performs a process in which a puncture hole in a vial closure made of a heat-fusible puncturable material is sealed using a source of heat, wherein the vial is conveyed adjacent the processing station using a conveyor system as claimed in any one of claims 14-24.

26. A processing station for performing an operation on an article in a laminar upstream to downstream direction flow of purified air which comprises; a processing apparatus for performing the operation upon the article, an aerodynamic shroud around at least part of the apparatus and positioned such that a leading surface of the aerodynamic shroud is upstream of the apparatus.

27. A processing station according to claim 26 wherein the processing station is configured to perform a vial-filling process in which a vial with a closure made of a heat-fusible puncturable material is conveyed to a position adjacent the processing station, and the processing station punctures the vial closure by passing a hollow filling needle through the closure, introduces a material into the vial via the needle, and withdraws the needle.

28. A processing station according to claim 26 or 27 wherein the processing station is configured to perform a process in which a puncture hole in a vial closure made of a heat-fusible puncturable material is sealed using a source of heat

30 29. A processing station according to claim 26, 27 or 28 mounted adjacent a conveyor system which is downstream of the processing station relative to the airflow and adapted to transport articles to a position adjacent the processing station.

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30. A processing station according to claim 29 wherein the conveyor system is as claimed in any one of claims 14 to 24.

5 31. A processing station according to any one of claims 26 to 30 wherein the shroud comprises two part-shrouds, elongated in a direction perpendicular to the direction of the laminar flow and to the plane of the cross section, hinged together at their respective leading edges to rotate about a hinge axis parallel to the elongate direction.

10 32. A process comprising puncturing a closure of a vial made of a heat-fusible puncturable material by passing a hollow filling needle through the closure, introducing a material preferably a medicament into the vial via the needle, then withdrawing the needle, wherein the needle comprises part of a processing station as claimed in any one of claims 26 to 31.

15 33. A process comprising sealing a puncture hole in a thermoplastic closure of a vial using a source of heat, wherein the source of heat comprises part of a processing station as claimed in any one of claims 26 to 31.

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